DEPARTMENT OF HEALTH & HUMAN SERVICES M1904 N Public Health Service

BUFFALO DISTRICT
Food and Drug Administration
599 Delaware Avenue
Buffalo, NY 14202

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

9 May 1997
WARNING LETTER BUF 97-16

Jack C. Bills, President
Adirondack Purification Co., Inc.
3885 Fennel Street
Skaneateles, New York 13152

Dear Mr. Bills:

An inspection of your firm was performed 8 November 1996 and 6 January 1997, by Food and Drug Administration Investigator David M. McNew. The inspection revealed your ozone generators are adulterated within the meaning of Section 501(f)(1)(B), and misbranded within the meaning of Sections 502(a), 502(f)(1), 502 (j), and 502(o), of the Federal Food, Drug and Cosmetic Act (the Act). The inspection also revealed your products fail to comply with Title 21, Code of Federal Regulations (CFR), Part 801.415, maximum acceptable level of ozone.

The Kleen Air-King II Portable Ozone Generators, Models 1001, 1004, 1004A, and 1004SP, and the Duct Air Purification & Disinfecting Systems, Models 1008A, 1008B, 1008C, and 1008F, are considered to be medical devices within the meaning of Section 201(h) of the Act. The devices are adulterated within the meaning of Section 501(f)(1)(B) of the Act, because they are classified under Section 513(f) into Class III and **they do not have an approved application for premarket approval (PMA) in effect pursuant to Section 515(a) or an approved application for an investigational device exemption (IDE) under Section 520(g).**

The devices are misbranded within the meaning of Section 502(a) of the Act, because the Kleen **Air-King models 1001, 1004, and 1004A labeling states these devices are adequate and effective at levels of ".045 ppm ozone", and further state they are intended to "eliminate odors and disease-spreading bacteria." Such representations or statements are false or misleading, or are otherwise contrary to fact, because the devices are not adequate or effective for such purposes [21 CFR 801.415(c)(5)].**

The devices are misbranded within the meaning of Section 502(f)(1) of the Act, because the **Adirondack Kleen Air II portable ozone generators and the Kleen Air Purification Systems bear inadequate directions for use for the purposes for which they are intended, including Models 1008, A, B, C and F, which do not indicate maximum concentrations of ozone in ppm by volume of air circulating through the devices [21 CFR 801.415(c)(1) and (c)(3)].**

The **Adirondack Kleen Air II portable ozone generator Model 1004SP** is misbranded within the meaning of Section 502(j) of the Act, because **the device is dangerous to health when used in the manner or with the frequency or duration prescribed, recommended, or suggested in the labeling. The labeling states a specification of .09 ppm ozone intended to disinfect and eliminate disease-spreading bacteria. This level is above the required concentration of .05 ppm ozone by volume of air circulating through the device, which can be injurious to health [21 CFR 801.415(c)(1)].**

The devices are further misbranded within the meaning of Section 502(o) of the Act because **your firm has not registered under Section 510, the devices were not included in a list required by Section 510(j), and notices or other information respecting the devices were not provided to the FDA as required by Section 510(k) of the Act.**

You should take prompt action to correct these violations, and establish procedures whereby such violations will not recur. Failure to achieve prompt corrections may result in regulatory action - **without further notice.** This may include seizure and/or injunction. Federal agencies are advised of the issuance of Warning Letters about devices so they may take this information into account when considering the award of contracts.

Please notify this office in writing, within fifteen days, of the specific steps you have taken to correct the noted violations and to prevent a recurrence of similar violations. Your response should be directed to Raymond D. Kent, Team Leader, at the above address.

Sincerely,

Edward W. Thomas
Acting District Director

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